Evidence to the Joint Committee on the Draft Health Service Safety Investigations Bill

June 2018

1. Introduction

1.1 The Professional Standards Authority for Health and Social Care promotes the health, safety and wellbeing of patients, service users and the public by raising standards of regulation and registration of people working in health and care. We are an independent body, accountable to the UK Parliament. More information about our work and the approach we take is available at www.professionalstandards.org.uk

1.2 As part of our work we:

- Oversee the nine health and care professional regulators and report annually to Parliament on their performance
- Accredit registers of healthcare practitioners working in occupations not regulated by law through the Accredited Registers programme
- Conduct research and advise the four UK governments on improvements in regulation
- Promote right-touch regulation and publish papers on regulatory policy and practice.

2. Key points

2.1 We welcome the opportunity to provide written evidence to the Joint Committee considering the Draft Health Service Safety Investigations Bill.

2.2 The Authority is supportive of efforts by the Government to encourage and promote a learning culture in healthcare where professionals openly discuss issues that have arisen and ways to improve patient care. We have consistently argued for reform of professional regulation in part to support a greater focus on learning. We are also aware that there are shortcomings in how serious healthcare incidents are investigated and that the proposals within the draft Bill are intended to address those.

2.3 We agree with Don Berwick *A promise to learn – a commitment to act*, that patient safety depends upon a learning culture, where near misses and errors are openly discussed and learnt from.[1] However, an open culture where information is shared between professionals must not be closed to patients and the public. The rights and needs of patients and their families, the

[1] National Advisory Group on the Safety of Patients in England, *A promise to learn– a commitment to act, Improving the Safety of Patients in England.* [Online] Available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/226703/Berwick_Report.pdf [Accessed: 08/06/2018]

accountability of professionals and the requirements of effective regulation should not be disregarded.

2.4 We have previously outlined our view that the proposals for the Health Service Safety Investigations Body (HSSIB) to carry out secret 'safe space' investigations contradicts the Government's commitment to transparency and accountability, as expressed though the legal and professional duty of candour and also conflicts with existing regulatory processes and the ability of regulators to protect the public.[2]

2.5 The proposals appear to be counter to the concept of a 'just culture' which the Government has previously shown support for in relation to other sectors and which has some acceptance within the NHS. [3] We note that the explanatory notes to the draft Bill reference 'a just culture of learning', however, the 'safe space' powers as proposed are contrary to our understanding of a just culture. We understand it to mean a culture which balances personal responsibility and accountability with shared accountability and an understanding of human behaviour. The Care Quality Commission's report 2016 on the way that trusts investigate deaths highlights the balance that needs to be struck between learning, candour and accountability for what has gone wrong.[4]

2.6 The proposals appear to go against the evidence that exists on the barriers to candour amongst health and care professionals which suggest that factors such as organisational culture, understanding of psychology and support for openness may have greater influence on whether professionals speak up when something has gone wrong.

2.7 There is currently a lack of clarity in relation to how proposals to allow HSSIB to accredit trusts to carry out 'safe space' investigations will operate in practice and a risk that these powers will be misused to prevent public scrutiny where things have gone wrong.

2.8 We are also concerned that this may create further problems for regulators in accessing the information they need from trusts to fully investigate and act on concerns where there may be a risk to public protection; and for patients and their families seeking information they expect.

2.9 We note the apparent contradiction in the powers for HSSIB to carry out maternity investigations outside 'safe space' powers which suggests recognition of the potential for lack of transparency.[5]

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[2] Professional Standards Authority, response to the consultation: *Providing a 'safe space' in healthcare safety investigations*, December 2016. [Online] Available at: https://www.professionalstandards.org.uk/docs/default-source/publications/consultation-response/others-consultations/2017/authority-response-to-dh-safe-spaces-final.pdf?sfvrsn=b79e7020_6 [Accessed: 04/06/2018]

[3] NHS Improvement, *A just culture guide*. [Online] Available at: https://improvement.nhs.uk/resources/just-culture-guide/ [Accessed: 08/06/2018]

[4] Care Quality Commission, *Learning, candour and accountability. A review of the way NHS trusts review and investigate the deaths of patients in England*. [Online] Available at: https://www.cqc.org.uk/sites/default/files/20161213-learning-candour-accountability-full-report.pdf

[5] The National Health Service Trust Development Authority (Healthcare Safety Investigation Branch) (Additional Investigatory Functions in respect of Maternity Cases) Directions 2018

'Safe space' powers

2.10 We believe that there is an inherent conflict between ‘safe space’ principles, the duty of candour and existing regulatory powers.

2.11 We are critical of the phrase ‘safe space’ which implies areas outside of it are not safe and potentially dangerous. This does not help foster better organisational trust or promote a ‘just culture’ in organisations, indeed it implies that the working environment is essentially unjust. The language of safe spaces is traditionally used in the protection of vulnerable children and adults.

2.12 As stated, the Authority is supportive of the Department of Health and Social Care’s aim of a culture of learning. In *Rethinking Regulation*, we noted Professor Gerry McGivern’s proposal for ‘reflective spaces’ where professionals can ‘discuss professional issues and problems freely with each other without fear of recrimination, and enquire freely of each other’.[6]

2.13 However, Professor McGivern’s proposals are fundamentally different from the proposals for ‘safe space’ investigations as they are intended to prevent harm occurring rather than providing protection in investigations when serious harm has already occurred. In addition, reflective spaces are intended to sit within regulatory systems, where professionals still ‘feel safe to openly discuss and address problems they might be facing in their practice’. This could be an important means of assuring patient safety and quality of care by addressing problems at an early stage but is not intended to be a way of avoiding personal responsibility once incidents of harm have occurred. We have seen this idea being taken up by a number of the professional regulators through their systems for assuring continuing fitness to practise, for example through the introduction of opportunities for peer discussion and reflection alongside traditional continuous professional development.[7]

2.14 As we understand it ‘safe spaces’ investigations would take professionals out of regulatory systems and lead to a number of potential unintended consequences.

2.15 A professional regulator’s purpose is to protect the public from harm, declare and uphold professional standards, and maintain public confidence in the profession. These three purposes clash with 'safe space' investigations as information found in an investigation will not readily be available to a regulator to investigate a concern. Regulators currently act on risk to patient safety by the imposition of interim orders for serious allegations. An interim order prevents the registrant from practising (interim suspension order), or places limits on their practice (interim conditions of practice order) until their case is

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https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/702938/NHS_Trust_Development_Authority__HSIB__Directions_2018.pdf

[6] *Rethinking Regulation*, Professional Standards Authority, pg. 18. Available at: http://www.professionalstandards.org.uk/docs/default-source/publications/thought-paper/rethinkingregulation-2015.pdf

[7] For example the General Pharmaceutical Council: https://www.pharmacyregulation.org/sites/default/files/document/gphc_revalidation_peer_discussion_guide_for_peers_april_2018.pdf

heard at a final panel hearing. This means that regulators are essential in defining what constitutes an immediate risk to the public and in acting to protect the public from immediate risk.

2.16 As currently outlined, HSSIB would be able to notify the relevant regulatory body: 'where any information, document, equipment or item may provide evidence of serious misconduct by any individual providing NHS services or managing the provision of those services'.[8] However, the proposals offer no detail on the threshold for when information gathered in a 'safe space' would to be handed over to a regulator. On what basis will the HSSIB determine that a matter is 'serious'? As we have highlighted in further detail later on, some of the interim bulletins on ongoing investigations, produced by the Healthcare Safety Investigations Branch include details of cases that in our view would be of relevance to regulators.

2.17 The proposals also outline that: 'the High Court may also order the HSSIB or an accredited trust to disclose information to a person if it determines that the interests of justice served by disclosing the information, document, equipment or item in question outweighs any adverse impact on future investigations by the HSSIB or accredited trusts by deterring persons from participating in them or the ability of the Secretary of State to secure the improvement of the safety of the NHS.'

2.18 However, the proposals do not explain how a regulator would know if information provided to a 'safe space' investigation but not brought to their attention warranted an appeal to the High Court for the release of the information. If regulators will be dependent on the judgement of those running 'safe space' investigations to identify issues which should be brought to their attention it will be essential to have clear protocols and defined thresholds. Information which may not seem important to investigators could be important for regulators in protecting the public. We have observed that some regulators are already reluctant to go to Court to seek information from criminal or civil proceedings needed for investigations, for example in child protection cases and we would have concern that the proposals will increase instances where such action would be required. Furthermore, the costs of applying to the Court can be significant and may create a further barrier to obtaining necessary information.

2.19 We note the lack of detail within the draft Bill on how the proposed powers would operate in practice. There are a number of other logistical issues which will need to be carefully considered, for example whether regulators, the authorities or HSSIB would have precedence if investigations were started simultaneously. Where there is a risk to patient safety we think that regulators should have priority.

2.20 We suggest that clarity is needed on what oversight will be in place for how HSSIB's exercise of its' powers.

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[8] The Department of Health, *Factsheet 3: The Draft Health Service Safety Investigations Bill 'Safe space': what is it, why we need it and how it will work*. [Online] Available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/644173/HSSIB_safe_space_fact__sheet.pdf [Accessed: 04/06/2018]

2.21 The impetus for a learning culture in healthcare is consistent with our thinking including our recent paper, *Right-touch reform*, which lays out our detailed proposals for the reform of professional regulation. In the paper we recommend a move from an adversarial to inquisitorial approach in fitness to practise proceedings and the need to ensure a greater focus on harm prevention through the sharing of data from regulatory processes and where appropriate, upstream interventions to address the causes of harm before it occurs.[9]

2.22 However, under the current legislative framework regulators have very specific powers to protect the public and the proposals for 'safe space' investigations are likely to make this more difficult. We would suggest that greater focus should be given to reforming and improving the current system so that it encourages and facilitates learning and improvement rather than proceeding with unnecessary additional powers which may have significant unintended consequences.

[9] Professional Standards Authority 2017, *Right-touch reform*. [Online] Available at: https://www.professionalstandards.org.uk/publications/detail/right-touch-reform-a-new-framework-for-assurance-of-professions [Accessed: 04/06/2018]

3. Annex 1 - Detailed answers to questions

General issues

Will the HSSIB command the confidence of patients and their families and healthcare professionals?

3.1 We refer you to our opening substantive comments regarding 'safe space' powers. We recognise the need for a new national approach to patient safety investigations with a focus on gathering learning to improve safety. However, while it is difficult to tell at this stage whether HSSIB as a body will command confidence, the lack of transparency associated with the 'safe space' powers of investigation and the conflict with the commitment to duty of candour may affect perceptions of the organisation.

3.2 We have recently published our *Lessons Learned Review into the Nursing and Midwifery Council's handling of concerns about midwives' fitness to practise at the Furness General Hospital*.[10] One of the key lessons from this was the need for openness with patients and their families and the problems that can arise when organisations act defensively and do not ensure transparency.

3.3 Whilst we recognise that healthcare professionals may be attracted to the idea of confidential, no-blame investigations where they can speak freely, in our view, as the powers proposed conflict with the professional and statutory duty of candour to patients and their families this would place professionals in a difficult position of being unable to comply with their duty of candour in relation to information disclosed as part of an investigation. As Bilton and Cayton outline in *Asymmetry of Influence*, professionals may become unreceptive when forced to try and reconcile different sets of standards and behavioural guidance.[11]

3.4 It is unclear whether individuals who provide information to an investigation will themselves be bound by a duty of confidentiality in relation to any information they disclose. If this is the case then it could also impact on the ability of healthcare professionals to access or provide information which may provide context or mitigation in the event of fitness to practise proceedings.

Should the HSSIB's remit extend to private healthcare?

3.5 We do not believe that it is helpful to have different structures in place for different parts of the health provision. Health and care professionals work across both private and publicly funded services and therefore it is important to have a consistent regulatory regime.

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[10] Professional Standards Authority 2018, *Lessons Learned Review into the Nursing and Midwifery Council's handling of concerns about midwives' fitness to practise at the Furness General Hospital.* [Online] Available at: https://www.professionalstandards.org.uk/publications/detail/nmc---lessons-learned-review-may-2018 [Accessed: 24/05/2018]

[11] D. Bilton and H. Cayton, *Asymmetry of Influence*. [Online] https://www.health.org.uk/publication/asymmetry-influence-role-regulators-patient-safety

Can patients and the public be confident that 'safe space' investigations will remedy the deficiencies of existing NHS complaints mechanisms?

3.6 Whilst we recognise a role for increasing learning from investigations into patient safety incidents we are unclear how the 'safe space' proposals can remedy concerns expressed about existing NHS complaints mechanisms.

3.7 Issues with the current systems in place for managing complaints have been well documented[12] as have the weaknesses of systems for investigating and learning from serious incidents.[13,14] However, as HSSIB will deal with only around 30 investigations a year and trusts are likely to focus full investigations on only the most serious incidents, this will not address the vast majority of complaints that are made across the health service.[15]

3.8 The 'safe space' proposals will also do little to address the common themes arising from many of the reviews of NHS complaints handling such as poor information available on how and where to complain, lack of clarity of process, promptness of response, support through the process and lack of transparency of resolution and action taken.

Are there any deficiencies in the drafting of the Bill that would prevent it from achieving the Government's objectives?

3.9 Yes, see our opening substantive comments on the 'safe space' powers.

3.10 We believe that as outlined the proposed 'safe space' investigation powers contradict the Government's stated commitment to the duty of candour and encouraging transparency in healthcare. The proposed powers also conflict with existing legislation which requires the health professional regulators to protect the public by ensuring the fitness to practise of all those on their professional registers.

3.11 We also believe that the proposals run counter to the evidence on the barriers to health professionals speaking up when things go wrong. This Bill may therefore be unsuccessful in encouraging a culture of learning and improvement. We previously carried out a review of the literature on barriers to candour to support advice to the Secretary of State on embedding the duty of candour amongst health and care professionals. Although concerns about personal repercussions, for example risk of litigation or effect on career do figure, there are a range of other factors which appear to be at least as important if not more so. These include the important of a positive workplace culture which supports speaking up, the impact of profession specific cultures

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[12] Anne Clwyd MP and Professor Tricia Hart, *NHS hospitals complaints system review*. [Online] Available at: https://www.gov.uk/government/publications/nhs-hospitals-complaints-system-review

[13] Parliamentary and Health Services Ombudsman, *A review into the quality of NHS complaints investigations*. [Online] Available at: https://www.ombudsman.org.uk/sites/default/files/A_review_into_the_quality_of_NHS_complaints_investigations_where_serious_or_avoidable_harm_has_been_alleged.pdf

[14] Department of Health Expert Group, *An organisation with a memory*. [Online] Available at: http://webarchive.nationalarchives.gov.uk/+/http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4065083

[15] Healthcare Safety Investigation Branch, *About us*. [Online] Available at: https://www.hsib.org.uk/about-us/ [Accessed: 08/06/2018]

which may encourage or inhibit candour and the importance of education and training in embedding a positive attitude to be open and honest about mistakes.[16]

3.12 We would also highlight that in the fitness to practise cases that we review under our statutory powers, we see a range of factors which impact on a professional's willingness to speak up when things go wrong.[17] For example, in the case of Macleod v Nursing and Midwifery Council, the registrant was not candid about abusive behaviour he had witnessed by a colleague towards a patient due to sense of misplaced loyalty to the colleague in question and to others in the workplace.[18] This reiterates the point that a 'safe space' is unlikely to encourage professionals to speak up in cases where the barriers to candour are wider and more complex than a simple fear of personal repercussions.

Establishment and powers

Will the establishment of the HSSIB add to confusion about the responsibilities of the various bodies currently dealing with complaints and safety concerns in healthcare?

3.13 Yes. As the oversight body for the health and care professional regulators we have seen first-hand some of the confusion that arises amongst members of the public when seeking resolution to complaints or concerns. This also leads to the health professional regulators receiving a large number of complaints which are not relevant to fitness to practise.

3.14 As we highlighted in *Rethinking regulation*: 'Today, we have more than 20 different regulatory agencies overseeing health and care. Each new organisation, and each new regulatory intervention, has been created in response to specific stimuli without the benefit of an overarching design, a controlling intelligence, or a coherent set of principles… It has led to a vastly complicated and incoherent regulatory system where the costs and benefits are unquantified and unclear. The different regulatory organisations, as we suggested above, have differences in legislation, standards, approach, and efficiency, amongst others.'[19] The HSSIB will add to this complexity and contradiction.

3.15 We believe that the system should better support learning from mistakes and we recognise the potential value of taking a wider view of healthcare safety incidents and helping to promote learning and improvement from

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[16] Professional Standards Authority, https://www.professionalstandards.org.uk/docs/default-source/publications/research-paper/candour-research-paper-2013.pdf?sfvrsn=5b957120_8

[17] Under our Section 29 powers we review the statutory professional regulators' final fitness to practise decisions and can appeal to the Courts if we think that any decision is 'insufficient to protect the public'.

[18] The Professional Standards Authority for Health and Social Care v The Nursing and Midwifery Council & Macleod [2014] EWHC 4354 (Admin) (19 December 2014) [Online] Available at: http://www.bailii.org/ew/cases/EWHC/Admin/2014/4354.html [Accessed: 08/06/2018]

[19] Professional Standards Authority 2015, *Rethinking regulation*. [Online] Available at: https://www.professionalstandards.org.uk/docs/default-source/publications/thought-paper/rethinking-regulation-2015.pdf?sfvrsn=edf77f20_14 [Accessed: 08/06/2018]

investigations. However, based on current proposals we are unclear how HSSIB and its powers fit with the existing regulatory structures. We are also unsure whether these benefits will be realised when the proposed powers for 'safe space' investigations risk frustrating the ability of the professional regulators to protect the public.

Would the draft Bill equip the HSSIB with adequate powers to achieve the Government's objective of improving patient safety, or the ability of the Secretary of State to secure the improvement of the safety of the NHS? Does it go too far in any respect?

3.16 See our opening substantive comments on 'safe space' powers. We believe that the draft bill goes too far in proposing 'safe space' investigation powers which conflict with the statutory and professional duty of candour and may restrict health professional regulators from carrying out their duty to protect the public by ensuring that health and care professionals are fit to practise.

Would it be appropriate to model the powers and status of the HSSIB more closely on similar bodies which investigate safety incidents in the aviation, rail or maritime industries?

3.17 No.

3.18 We note the useful lessons which Macrae has drawn from the airline and other safety critical industries. He discussed the need for the UK healthcare system to develop a system of 'participative risk regulation' whereby all staff see patient safety as part of their role and responsibility.[20] The idea of 'shared accountability' has been developed within the aviation sector in response to avoidable aviation disasters. Pilots, air traffic control, mechanics and other personnel all give each other permission to constructively challenge and check each other's decisions. The Authority has been supportive of this concept of 'constructive challenge' in previous policy documents as a possible model of improving the learning culture in healthcare.[21]

3.19 However, the airline and health industries are not analogous as Kapur, Parand, Soukup, Reader and Sevdalis have outlined.[22] The limits to which comparisons can be drawn between the two sectors on the issue of 'safe spaces' is most pronounced with regard to professional regulation. Pilot licensing is not as complex as health and care professional regulation. Health and care regulators have public facing registers which provide details of a registrant's impairment, sanctions and detailed reasons for sanctions.[23] It should also be noted that the drivers for revealing information to regulators are markedly different between the airline and health industries.

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[20] *Learning from patient safety incidents: Creating participative risk regulation in healthcare*, Carl Macrae. [Online] Available at: http://www.tandfonline.com/doi/abs/10.1080/13698570701782452

[21] Professional Standards Authority 2015, *Rethinking Regulation*, pg. 19

[22] *Aviation and healthcare: a comparative review with implications for patient safety*, Narinder Kapur, Anam Parand, Tayana Soukup, Tom Reader and Nick Sevdali, pp 1-2. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4710114/table/table1-2054270415616548/

[23] For example the Nursing and Midwifery Council's: https://www.nmc.org.uk/concerns-nursesmidwives/hearings-and-outcomes/hearings-sanctions/hearings-november-2016/

3.20 Whilst we believe that lessons can be learned from other sectors including the aviation industry, it is important to recognise the clear differences and adapt powers and approaches accordingly. We suggest that the proposed powers for HSSIB to carry out 'safe space' investigations do not sufficiently recognise the differences and specific context in healthcare.

Does the draft Bill ensure that the HSSIB is sufficiently independent of both the NHS and the Government?

3.21 As currently outlined in the draft Bill, HSSIB will operate as an arm's length body (ALB) in a similar way to investigation bodies in the rail and aviation sector. Whilst this will provide a degree of independence and will ensure separation of HSSIB from the NHS, there may still be a perceived lack of independence as HSSIB will be accountable to the Secretary of State (SoS). This may also create a perception that the SoS has a level of direct responsibility for decisions made by HSSIB and the way that it operates.

Safe space

Is a legally protected 'safe space' necessary to successfully undertake NHS investigations?

3.22 No, we refer you to our substantive opening comments on the safe space powers.

3.23 We recognise that the Healthcare Safety Investigation Branch (HSIB)[24] is in the early days of operation and hasn't yet completed a full investigation or published a final report and that it doesn't yet have 'safe space' powers. However, to illustrate our concerns about how the proposed powers could impact on current professional regulatory arrangements, we have referred to some of the interim bulletins on investigations produced by HSIB which include details of cases that in our view would be of relevance to regulators.

3.24 An example is the interim report on 'wrong route of administration of an oral drug into a vein'.[25] This is something that comes up regularly in the fitness to practise cases which we scrutinise under our powers. The report refers to 61 incidents between 1 April 2016 to 30 November 2017. Potentially all of these should have been reported to the regulator given the risks involved. Depending on the particular circumstances, single incident cases where the registrant demonstrated remorse and had undertaken remediation might not meet the test for referral to a hearing and may be closed at by the regulator at an earlier stage. However, if there are associated issues around repetition by an individual or lack of candour in raising the error, then this might suggest the need for much more serious action. Ultimately the regulator must be able to form an independent view of the facts of the case and make a decision on what action is required to protect the public.

[24] The Healthcare Safety Investigation Branch (HSIB) will become the Health Service Safety Investigation Body (HSSIB) if the draft Bill becomes law.
[25] Healthcare Safety Investigation Branch, *Wrong route administration of an oral drug into a vein – Interim bulletin*. [Online] Available at: https://www.hsib.org.uk/investigations-cases/notification-investigation-wrong-route-administration-oral-drug-vein/ [Accessed: 08/06/2018]

3.25 As noted, the threshold for when HSSIB will disclose information is not defined in the Bill but we include the above example to highlight that the information which they are looking at as part of their investigations may well be relevant to professional regulators and it will be essential that there are clear criteria on when information should be shared outside of a 'safe space' investigation.

3.26 We also note that NHS Improvement is currently consulting on guidelines for investigations conducted outside of the scope of the safe space powers.[26] We do not believe that 'safe space' powers are necessary for effective learning to be gained from investigating why things when wrong and developing recommendations to improve patient safety.

3.27 The is also an apparent contradiction in the new powers for HSSIB to carry out maternity investigations but not under 'safe space' powers.[27] Whilst we recognise that this relates to individual rather than thematic investigations this suggests some recognition of the potential for a perception of lack of transparency and highlights some of the inherent contradictions with existing Government policy in relation to the duty of candour.

3.28 In our view it is entirely possible for useful and practical learning to be gathered without the use of 'safe space' powers which may have significant unintended consequences.

Will creating a 'safe space' for safety investigations "encourage patients, families, NHS staff and other participants in an HSSIB investigation to speak freely for the purposes of promoting learning and improving safety"?

3.29 We believe that whilst there may be some benefits the risks of such investigations may outweigh these.

3.30 As we understand it, the proposals are intended to provide protection to professionals providing information as part of a 'safe space' investigation and therefore it is misleading to suggest that this provides safety for patients and their families in the same way.

3.31 The duty of candour has been a key focus for the NHS over the last few years. The introduction of the statutory duty of candour was to 'ensure that providers are open and transparent with people who use services' and this was echoed in a joint statement by eight of the UK professional regulators.[28] 'Safe space' investigations may be perceived by patients and their families to be contrary to the expectation of greater honesty and openness by professionals. This may

[26] NHS Improvement, Consultation - The future of NHS patient safety investigation. [Online] Available at: https://improvement.nhs.uk/resources/future-of-patient-safety-investigation/ [Accessed: 08/06/2018]
[27] The National Health Service Trust Development Authority (Healthcare Safety Investigation Branch) (Additional Investigatory Functions in respect of Maternity Cases) Directions 2018 https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/702938/NHS_Trust_Development_Authority__HSIB__Directions_2018.pdf
[28] Professional Standards Authority, *Progress on strengthening professional regulation's approach to candour and error reporting*, pg. 5. [Online] Available at: http://www.professionalstandards.org.uk/docs/default-source/publications/advice-to-ministers/progress-on-strengthening-approach-to-candour-november-2014.pdf [Accessed: 04/06/2018]

affect the willingness of participants, particularly patients and families to engage with investigations.

3.32 Although the Bill and associated documentation suggests that a 'safe space' is required to encourage professionals to speak freely we refer you to paragraphs 3.11-3.12 where we referred to the literature review which we carried out in examining the barriers to professionals demonstrating candour. In it we found that factors such as organisational culture, professional culture and education and training were as important in preventing or promoting candour as individual barriers to candour such as concerns about impact on career or the risk of litigation.[29]

3.33 We welcome the fact that the draft Bill includes provision to make HSSIB subject to the Freedom of Information Act, however, we need clarity on how this will operate in practice. We believe FOI requests make organisations accountable to the public and foster greater public trust in an organisation's operations. There is an expectation of transparency on the part of patients, families and the public. However, FOI requests may be unlikely to yield meaningful results if information is provided in a heavily redacted form or withheld under the exceptions of the Act. A commitment to transparency needs to be evidenced in practice as well as in principle.

Would the draft Bill adequately protect from disclosure information given to the HSSIB?

3.34 We do not agree that this should be a priority for HSSIB and that protecting information from disclosure will conflict with the duty of candour and public trust in openness and transparency in healthcare and operational difficulties for regulators in accessing information they need to protect the public.

3.35 As noted in 3.4 we are unclear whether individuals who provide information to an investigation will themselves be bound by a duty of confidentiality in relation to any information they disclose. As we understand it, there will be a prohibition on disclosure of information provided as part of a 'safe space' investigation by either HSSIB itself or an accredited trust. However, the Bill does not appear to state whether this prohibition will extend to witnesses participating in an investigation e.g. professionals, patients or their families.

3.36 If the intention is for those providing information to an investigation to be prevented from revealing what they know more widely then this could conflict with individuals' professional duty of candour as well as their duty to inform their regulator if they are aware of a risk to patient safety.

[29] Professional Standards Authority 2013, *Candour, disclosure and openness - Learning from academic research to support advice to the Secretary of State*. [Online] Available at: https://www.professionalstandards.org.uk/docs/default-source/publications/research-paper/candour-research-paper-2013.pdf?sfvrsn=5b957120_8 [Accessed: 08/06/2018]

Accreditation

Will the public have confidence in trusts carrying out their own 'safe space' investigations, and will this build public confidence in the NHS safety investigations system more generally?

3.37 We doubt it. We recognise the history of poor quality of local complaints handling and the negative experiences of many patients and service users in seeking to navigate the system. We note one of the conclusions from the 2014 HealthWatch report into the system for complaints handling: 'In order to use complaints to drive improvements, we must first have a system that is simple, compassionate and responsive to those making the complaints.'[30] There is little in the HSSIB proposals that will make the system work better for those seeking resolution through it.

3.38 We have recently published our *Lessons Learned Review into the Nursing and Midwifery Council's handling of concerns about midwives' fitness to practise at the Furness General Hospital*.[31] In this report we highlighted issues that had arisen with the trust's handling of the initial investigation and the challenges of accessing information needed for the fitness to practise process. Whilst the public will expect trusts to learn from incidents and ensure that processes are improved to avoid harm in the future, we do not believe that there is likely to be confidence in trusts using 'safe space' powers as this will conflict with the greater emphasis on transparency and openness that is required. Furthermore, if trusts are able to investigate themselves on this basis there is the risk that 'safe space' powers may be used by trusts when there is a risk of reputational damage and they wish to keep information from proper public scrutiny. Our lessons learned review highlights the issues that can arise currently if a trust does not fully cooperate with a regulator.

3.39 We have been critical of over-reliance on local investigation reports but we know that regulators often rely on information gathered by trusts to feed into fitness to practise proceedings or build a case. If trusts are to be given powers to operate investigations in secret this may create further problems for regulators in accessing information required to act on concerns where there may be a risk to public protection and for patients and their families seeking answers. It may also introduce delays in what can already be a lengthy, protracted process, causing further stress to those involved.

Are the accreditation provisions in the draft Bill satisfactory?

3.40 No, there is a lack of clarity on how HSSIB will assess whether trusts are competent to run 'safe space' investigation and ensure that such powers are not being misused to prevent public scrutiny of patient safety incidents. It is

[30] https://www.healthwatch.co.uk/complaints/report

[31] Professional Standards Authority 2018, *Lessons Learned Review into the Nursing and Midwifery Council's handling of concerns about midwives' fitness to practise at the Furness General Hospital.* [Online] Available at: https://www.professionalstandards.org.uk/publications/detail/nmc---lessons-learned-review-may-2018 [Accessed: 08/06/2018]

also unclear whether HSSIB will have the capacity to assess and monitor the use of such powers on an ongoing basis.

Will the HSSIB be able to maintain standards of investigation?

3.41 See answer above.

Reporting

Will the HSSIB be able to effect change and ensure its recommendations are acted upon?

3.42 We would welcome further information on how HSSIB intends to work with other organisations to ensure that findings from its investigations are acted on and improvements are made. The duty of cooperation between HSSIB and other bodies referred to in the draft Bill is welcome but further detail is needed on how this will work in practice.

3.43 For example, it will be important to provide clarity on how investigations will be sequenced if both the regulator and HSSIB become aware of incidents at the same point. It is common for regulators to delay final fitness to practise hearings to allow criminal proceedings to conclude. We have suggested that where there is a risk to patient safety regulators should be given priority.

3.44 We would suggest that if the proposed 'safe space' powers force other bodies to go to the Courts to access information they require this may not encourage joint working and may hamper effective cooperation and information sharing to improve patient safety.

Would there be adequate safeguards for people referred to in HSSIB reports?

3.45 See previous comments at paragraphs 3.4 and 3.35. We are unclear whether the 'safe space' powers will prevent those taking part in HSSIB investigations from providing relevant information to other bodies, for example under their responsibilities as a registered professional or under the duty of candour and if so whether the potential consequences for individuals involved have been fully considered. We do not consider that health professionals should have privileged legal status in any investigation.

4. Further information

4.1 Please get in touch if you would like to discuss any aspect of this response in further detail. You can contact us at:

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